REMARKS

This is in response to the Official Action of March 23, 2004. Reconsideration in light of the remarks below is respectfully requested.

The amendments made herein were denied entry after final in applicant's previous response as raising "new issues".

Claim 10 is amended for consistency with the other dependent claims. New claims 47-49 are directed to specific embodiments and are added to complete the record.

The withdrawal of the rejections not reenumerated in the Official Action is acknowledged with appreciation.

Enablement rejection. Claims 1-10 stand rejected as lacking enablement under the first paragraph of 35 USC 112. Reconsideration in light of the remarks set forth below is respectfully requested.

The nature of the invention and the breadth of claims. In the Official Action it is alleged that the claims are broadly drawn to any proliferative disorder. This is incorrect. The claims have been previously amended to focus on a preferred category of disorders, and are further amended above to focus on a particularly preferred category of disorders. Hence the scope of the claims with respect to disease is not particularly broad. With respect to subjects, the term subjects is defined in the specification to be primarily human subjects, or other animal subjects for veterinary purposes (page 10, lines 6-8). Persons skilled in the art would readily appreciate which veterinary subjects could be utilized in like manner to human subjects, and hence it is believed the scope of the claims with respect to subjects is not particularly broad. If the Examiner would suggest that this case could be placed in allowable form by amending the claims to direct them to human subjects applicants would certainly be amenable to such suggestion.

The teachings of the specification and working examples. Applicants previous remarks on this point are incorporated herein by reference.

The unpredictability of the art and the state of the prior art. In the Official action it is alleged that there is a great deal of unpredictability in the exprression of nucleic acids as indicative of diseases. Applicants note, however, that the United States Patent and Trademark Office has issued **more than five hundred patents** that are categorized in class 436 (Chemistry:

Analytical and Immunological testing), subclass 813 (test for named disease, body function or organ condition: Cancer). Clearly the presently claimed invention is not in a speculative or incredible field of endeavor.

The Official Action is critical of data on melanoma or pancreas cell lines, but pancreatic cancer was not presented in the previous claims, and melanoma has been dropped in the amendment above to narrow the issues.

State of the art. While this factor is grouped together with unpredictability of the art in the Official Action, it is submitted that this factor should be addressed separately. Given that the CLN3 gene is known and that numerous techniques for assaying gene expression are known and available to those skilled in the art (as reflected by the great number of patents issued in the cancer testing area noted above), the state of the prior art in this field is alleged to be high.

Quantity of Experimentation The quantity of experimentation required to practice the invention is alleged in the official action to be high. No facts are presented in support of this allegation. Applicants allege to the contrary that the quantity of experimentation required to practice the claimed invention, given what the high state of the art and the high level of skill in the art, and the simple nature of the tests required to carry out the claimed invention. At best any experimentation needed to carry out the claimed invention is routine.

Level of skill in the art. The level of skill in the art is deemed to be high in the official action, and applicants agree with this assessment in the context of the current issue under 35 USC 112.

Guidance in the specification. It is alleged that the specification establishes little guidance fo carrying out the present invention. However, the Official Action focuses on the quantity of proof presented and not on the amount of guidance presented. What is claimed is a diagnostic assay with a particular known gene for a particular list of disorders. Given the high state of the art and the high level of skill in the art, there is seen no factual basis for the statement under this *Wands* factor that further research into the claimed method would be undue.

In view of the foregoing, it is respectfully submitted that the claims of record satisfy the enablement requirement set forth in 35 USC 112, and respectfully submitted that this application should be allowed.

Respectfully submitted,

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